

WHAT IS CLAIMED IS:

1. A method for ~~substantially~~ reducing the range in daily dosages required to control pain in human patients, comprising administering an oral controlled release dosage formulation comprising from about 10 to about 40 mg oxycodone or a salt thereof which provides a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 30 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.

2. A method for ~~substantially~~ reducing the range in daily dosages required to control pain in substantially all human patients, comprising administering an oral solid controlled release dosage formulation comprising from about 10 mg to about 160 mg oxycodone or a salt thereof which provides a mean maximum plasma concentration of oxycodone up to about 240 ng/ml from a mean of up to about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration up to about 120 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.

3. A controlled release oxycodone formulation for oral administration to human patients, comprising from about 10 to about 40 mg oxycodone or a salt thereof, said formulation providing a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 30 ng/ml from a mean of about 10 to about 14 hours after

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repeated administration every 12 hours through steady-state conditions.

4. A controlled release oxycodone formulation for oral administration to human patients, comprising from about 10 mg to about 160 mg oxycodone or a salt thereof, said formulation providing a mean maximum plasma concentration of oxycodone from about 6 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 120 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.

5. A solid controlled release oral dosage form, comprising

(a) oxycodone or a salt thereof in an amount from about 10 to about 160 mg;

(b) an effective amount of a controlled release matrix selected from the group consisting of hydrophilic polymers, hydrophobic polymers, digestible substituted or unsubstituted hydrocarbons having from about 8 to about 50 carbon atoms, polyalkylene glycols, and mixtures of any of the foregoing; and

(c) a suitable amount of a suitable pharmaceutical diluent, wherein said composition provides a mean maximum plasma concentration of oxycodone from about 6 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 120 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.

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6. The controlled release composition of claim 5, wherein said controlled release matrix comprises an acrylic resin.

5 7. A solid controlled release oral dosage form, comprising

(a) an analgesically effective amount of spheroids comprising oxycodone or a salt thereof and either a spheronising agent or an acrylic polymer or
10 copolymer, such that the total dosage of oxycodone in said dosage form is from about 10 to about 160 mg;

(b) a film coating which controls the release of the oxycodone or oxycodone salt at a controlled rate in an aqueous medium, wherein said composition provides
15 an in vitro dissolution rate of the dosage form;

said composition providing a mean maximum plasma concentration of oxycodone from about 6 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration
20 from about 3 to about 30 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.

8. The controlled release composition of claim 7,
25 wherein said film coating comprises a water insoluble material selected from the group consisting of shellac or zein, a water insoluble cellulose, or a polymethacrylate.

9. A controlled release tablet for oral administration comprising from about 10 to about 160 mg oxycodone or an oxycodone salt dispersed in a controlled release matrix, said tablet providing an in-vitro dissolution of the dosage form, when measured by the USP Paddle Method at 100 rpm at 900 ml aqueous buffer (pH
35 between 1.6 and 7.2) at 37° C, between 12.5% and 42.5%

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(by wt) oxycodone released after 1 hour, between 25% and 55% (by wt) oxycodone released after 2 hours, between 45% and 75% (by wt) oxycodone released after 4 hours and between 55% and 85% (by wt) oxycodone released after 6 hours, the in vitro release rate being substantially independent of pH and chosen such that a mean maximum plasma concentration of oxycodone from about 6 to about 240 ng/ml is obtained in vivo from a mean of about 2 to about 4.5 hours after administration of the dosage form, and a mean minimum plasma concentration from about 3 to about 30 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.

10. A dosage form according to claim 9, wherein the in vitro dissolution rate is between 17.5% and 38% (by wt) oxycodone released after 1 hour, between 30% and 50% (by wt) oxycodone released after 2 hours, between 50% and 70% (by wt) oxycodone released after 4 hours and between 60% and 80% (by wt) oxycodone released after 6 hours.

11. A dosage form according to claim 9, wherein the in vitro dissolution rate is between 17.5% and 32.5% (by wt) oxycodone released after 1 hour, between 35% and 45% (by wt) oxycodone released after 2 hours, between 55% and 65% (by wt) oxycodone released after 4 hours and between 65% and 75% (by wt) oxycodone released after 6 hours.

ABSTRACT OF THE DISCLOSURE

A method for substantially reducing the range in daily dosages required to control pain in approximately 90% of patients is disclosed whereby an oral solid controlled release dosage formulation having from about 10 to about 40 mg of oxycodone or a salt thereof is administered to a patient. The formulation provides a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 30 ng/ml from about 10 to about 14 hours after repeated "q12h" (i.e., every 12 hour) administration through steady-state conditions. Another embodiment is directed to a method for substantially reducing the range in daily dosages required to control pain in substantially all patients by administering an oral solid controlled release dosage formulation comprising up to about 160 mg of oxycodone or a salt thereof, such that a mean maximum plasma concentration of oxycodone up to about 240 ng/ml from a mean of up to about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration up to about 120 ng/ml from about 10 to about 14 hours after repeated "q12h" (i.e., every 12 hour) administration through steady-state conditions are achieved. Controlled release oxycodone formulations for achieving the above are also disclosed.



U.S.A.
DECLARATION AND POWER OF ATTORNEY

93-311

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

CONTROLLED RELEASE OXYCODONE COMPOSITIONS

the specification of which (check one) ☒ is attached hereto.

☐ was filed on _____ as Application Serial No. _____ and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose all information which is known to me to be material to the patentability of this application as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

PRIOR FOREIGN APPLICATION(S)

Priority
claimed

(Number) _____	(Country) _____	(Day/Month/Year filed) _____	<input type="checkbox"/> Yes	<input type="checkbox"/> No
(Number) _____	(Country) _____	(Day/Month/Year filed) _____	<input type="checkbox"/> Yes	<input type="checkbox"/> No
(Number) _____	(Country) _____	(Day/Month/Year filed) _____	<input type="checkbox"/> Yes	<input type="checkbox"/> No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

07/800,549	November 27, 1991	Pending
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
PCT/US92/10146	November 25, 1992	Pending
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

And I hereby appoint Harold D. Steinberg, Registration No. 17, 255, Martin G. Raskin, Registration No. 25,642, and Clifford M. Davidson, Registration No. 32,728 my attorneys, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith; correspondence address: STEINBERG & RASKIN, 1140 Avenue of the Americas, New York, N.Y. 10036; Telephone: 212-768-3800; Fax: 212-382-2124.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first

Inventor, if any Benjamin OSHLACK

Third inventor's signature Benjamin Oshlack

Date 14 May 1993

Residence New York, NY

Citizenship Australia

Post Office Address 351 East 84th Street
New York, NY 10028

Full name of joint

Inventor, if any Mark CHASIN

Fourth inventor's signature Mark Chasin

Date May 14, 1993

Residence Manalpan, New Jersey

Citizenship U.S.A.

Post Office Address 3 Wayne Court
Manalpan, NJ 07726

Full name of joint

Inventor, if any John Joseph MINOGUE

Third inventor's signature John Joseph Minogue

Date May 14, 1993

Residence Mount Vernon, NY

Citizenship U.S.A.

Post Office Address 33 East Grand Street, B-2B
Mount Vernon, NY 10552

Full name of joint

Inventor, if any Robert FRANCIS KAICO

Fourth inventor's signature Robert Francis Kaico

Date May 14, 1993

Residence Weston, Connecticut

Citizenship U.S.A.

Post Office Address 10 Norfield Woods Road
Weston, CT 06883

Full name of joint

Inventor, if any _____

Fifth inventor's signature _____

Date _____

Residence _____

Citizenship _____

Post Office Address _____

Full name of joint

Inventor, if any _____

Sixth inventor's signature _____

Date _____

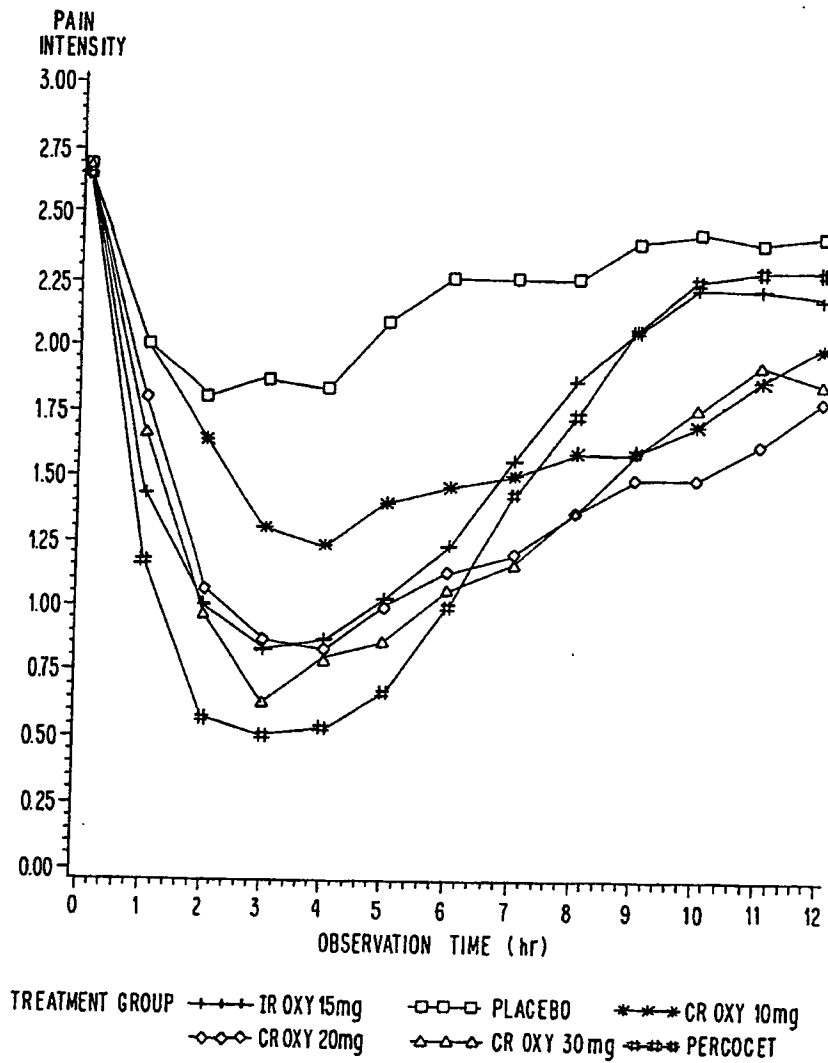
Residence _____

Citizenship _____

Post Office Address _____

'042 - 46

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**FIG. 1**

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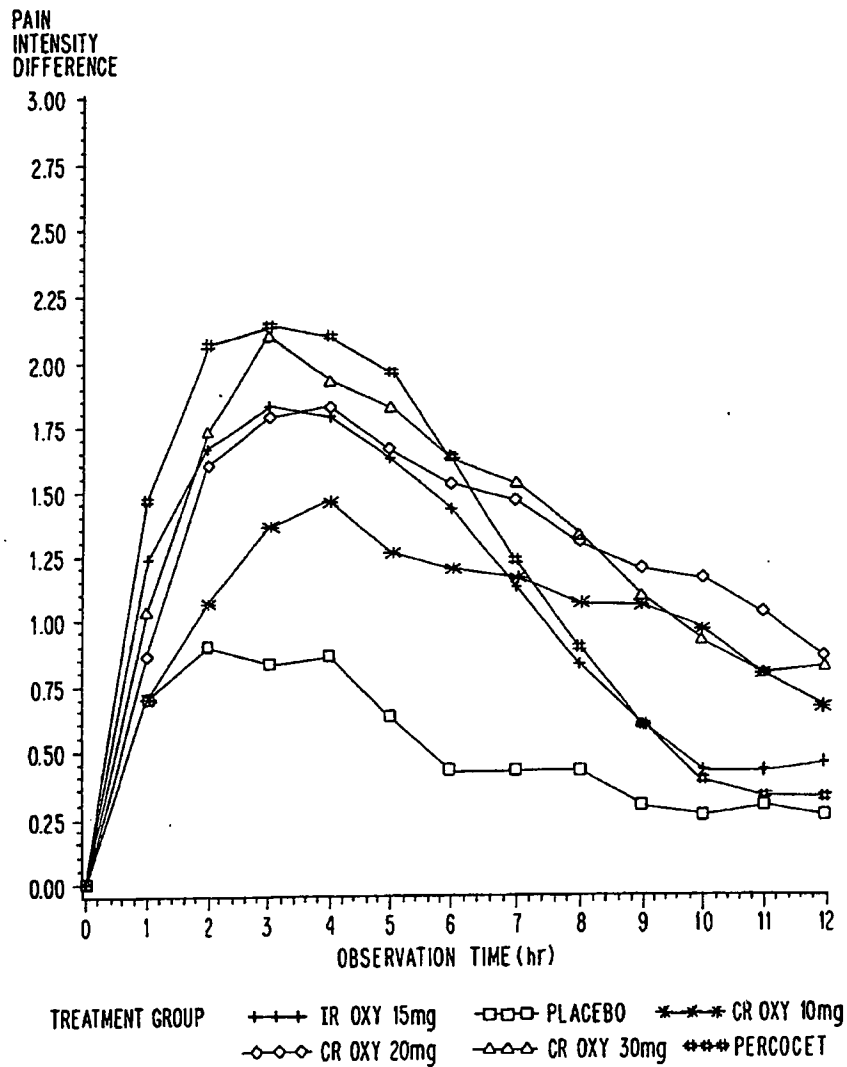


FIG.2

08/467584

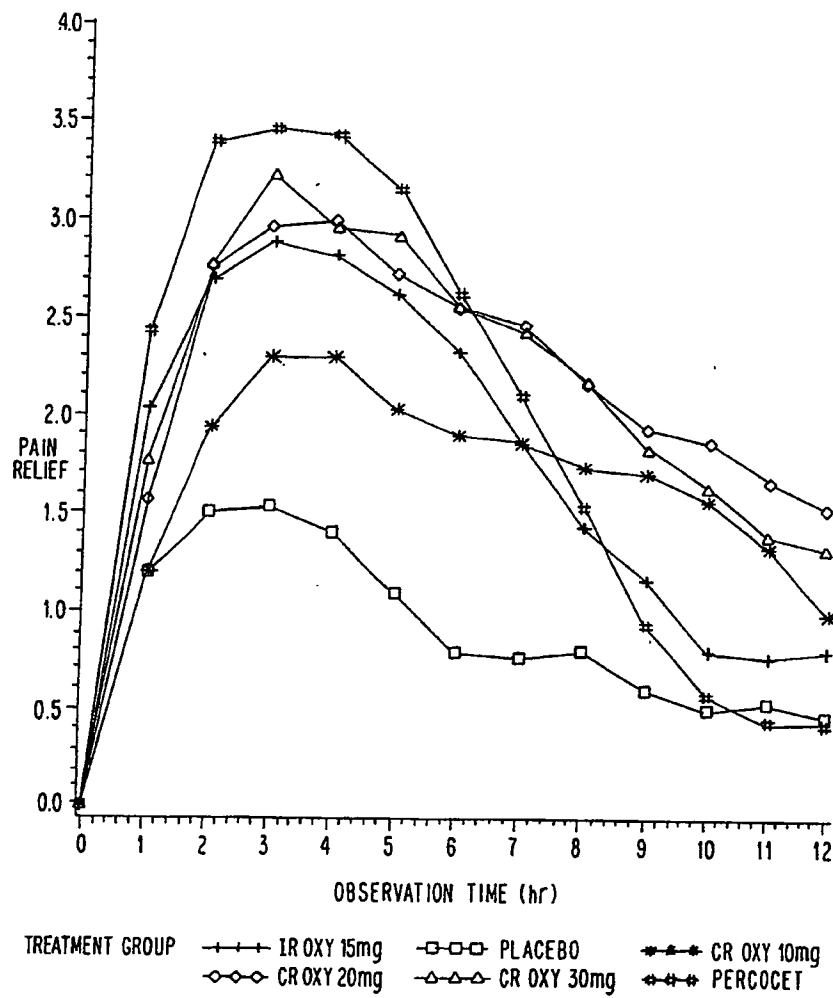


FIG. 3

08/467584

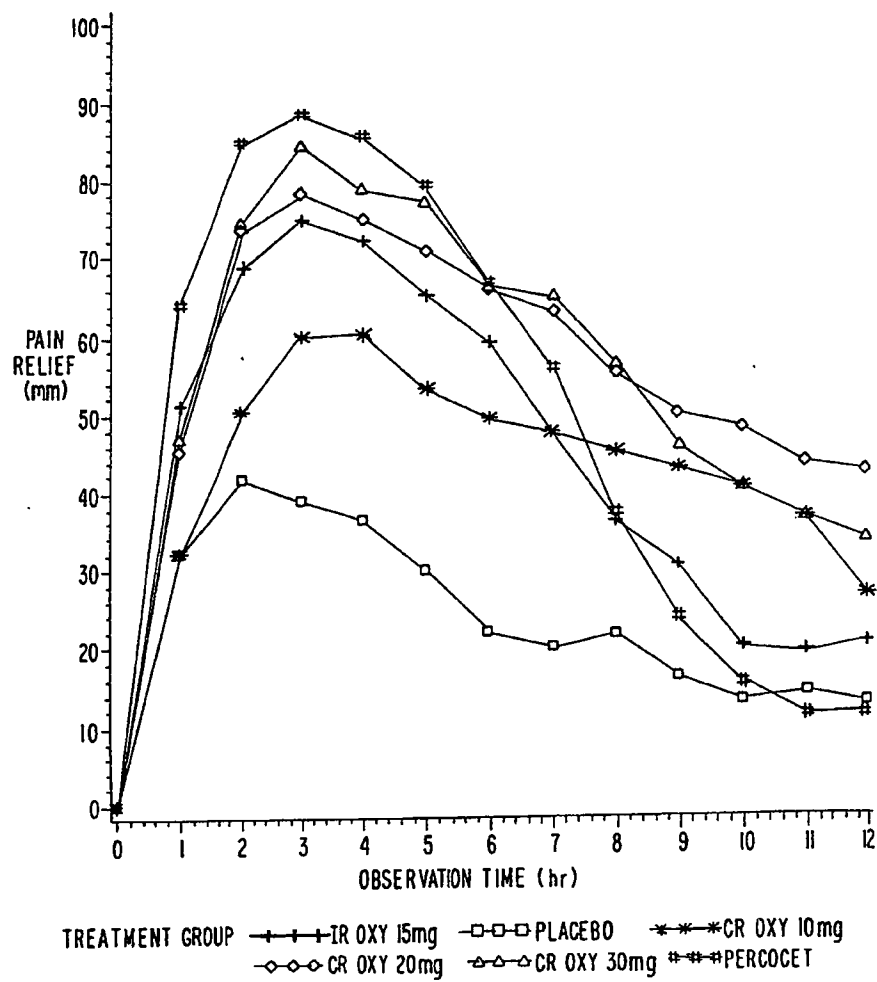
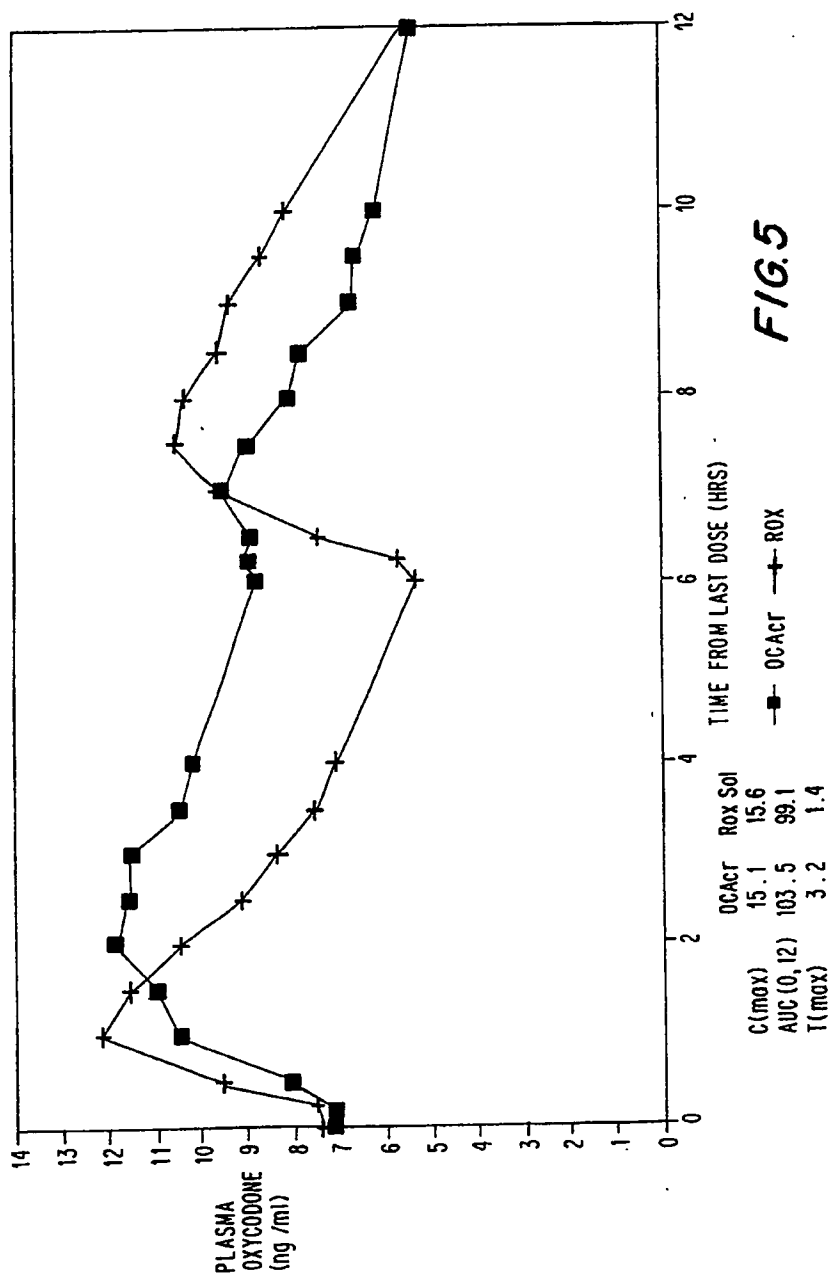


FIG. 4

08/467584



'042 - 51



730-1A
08/467584 A

FORM 54 (MODIFIED)
DIVISIONAL-CONTINUATION PROGRAM APPLICATION
TRANSMITTAL FORM

2/a
D. Cassaway
8-14-95

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Docket No. 20093311.DIV

Anticipated Classification of this application:

Class 514
Subclass 282

Prior application: 08/081,302

Examiner E. Webman
Art Unit 1502

The Commissioner of
Patents and Trademarks
Washington, D.C. 20231

June 6, 1995

Sir:

This is a request for filing a divisional application under 35 C.F.R. §1.60 of pending prior application Serial No. 08/081,302, filed on June 18, 1993.

For: CONTROLLED RELEASE OXYCODONE COMPOSITIONS

1. ☒ Enclosed is a copy of the prior application including the oath or declaration as originally filed and an affidavit or declaration verifying it as a true copy. (See 8 and 8a for drawing requirements.)
2. ☐ Prepare a copy of the prior application.

"Express Mail" mailing label no. TB 639 428 042 US
Date of deposit: June 6, 1995
I hereby certify that this correspondence and/or fee is being deposited with the United States Postal Service "Express Mail" service under 37 CFR 1.10 on the date indicated above in an envelope addressed to "Commissioner of Patents and Trademarks, Washington, DC 20231" STEINBERG, RASKIN & DAVIDSON, P.C.

BY: Oliver Chisari

3. ☒ The filing fee is calculated below:

CLAIMS AS FILED IN THE PRIOR APPLICATION LESS ANY CLAIMS CANCELLED BY AMENDMENT BELOW				
For	Number filed	Number extra	Rate	Basic fee \$730.00
Total claims	2 - 20 =	0	× 22	0.00
Independent claims	2 - 3 =	0	× 76	0.00
Total filing fee				\$730.00

4. ☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Account No. 19-4210. A duplicate copy of this sheet is enclosed.
5. ☒ A check in the amount of \$730.00 is enclosed.
6. ☒ Cancel in this application original claims 3-11 of the prior application (without prejudice) before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)
7. ☒ Amend the specification by inserting before the first line the sentence: This is a divisional of application Serial No. 08/081,302, filed June 18, 1993, which is a continuation-in-part of U.S. Application Serial No. 07/800,549, filed November 27, 1991, now U.S. Patent No. 5,266,331.

8. ☐ Transfer the drawings from the prior application to this application and abandon said prior application as of the filing date accorded to this application. A duplicate copy of this sheet is enclosed for filing in the prior application file. (May only be used if signed by person authorized by Rule 138 and before payment of base issue fee.)

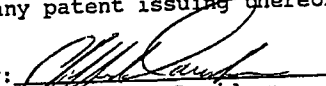
8a. ☒ New formal drawings are enclosed.

8b. ☐ Priority of application in Serial No. filed on under 35 U.S.C. §119.

☐ The certified copy has been filed in prior application, Serial No. , filed .

9. [X] The prior application is assigned of record to Euroceltique, S.A.
10. [X] The power of attorney in this prior application is to Harold D. Steinberg, Reg. No. 17,255, Martin G. Raskin, Reg. No. 25,642, and Clifford M. Davidson, Reg. No. 32,728, 1140 Avenue of the Americas, New York, N.Y. 10036.
- a. [X] The power appears in the original papers in the prior application.
- b. [] Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.
- c. [X] Address all future communications to Steinberg, Raskin & Davidson, P.C., 1140 Avenue of the Americas, New York, N.Y. 10036, Tel. (212) 768-3800.
11. [] A preliminary amendment is enclosed. (Claims added by this amendment have been properly numbered consecutively beginning with the number next following the highest numbered original claim in the prior application).
12. [X] I hereby verify that the attached papers are a true copy of prior application Serial No. 08/081,302, as originally filed on June 18, 1993.

The undersigned declare further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that those statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By: 
Clifford M. Davidson
Attorney of Record
Reg. No. 32,728

Steinberg, Raskin & Davidson, P.C.
1140 Avenue of the Americas
New York, New York 10036
(212) 768-3800

B:\20093311.DIV


**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

 Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/16/95 08/16/95 1502/1103

 10.
STEINBERG RASKIN & DAVIDSON
1140 AVENUE OF THE AMERICAS
NEW YORK NY 10036

WEIDMAN, E

EXAMINER

ART UNIT PAPER NUMBER

1502

11/03/95 3

DATE MAILED:

 This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

 A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133
Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1, 2 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1, 2 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-328 (Rev. 2/83)

'042 - 55

Serial Number: 08/467,584

-2-

Art Unit: 1502

Claims 1, 2 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to that which is disclosed as critical. See M.P.E.P. §§ 706.03(n) and 706.03(z).

On page 11, lines 24-28 a ratio of hydroxyalkyl cellulose to aliphatic alcohol or polyalkylene glycol of 1:2-1:4 is disclosed as determinative of the release rate of oxycodone. No other ratio is specified. However, claims 1, 2 specify no ratio at all. Thus, the specification is insufficient to support the breadth of the claims.

Claims 1, 2 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

No where in claims 1, 2 is the vehicle disclosed which delivers the active agent at the claimed rate. No ingredients are specified.

Serial Number: 08/467,584

-3-

Art Unit: 1502

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention.

On page 10, line 31 - page 11, line 13 suggested ingredients are recited.

However, it is unclear precisely which are present in the vehicle, since all are optional.

Claims 1, 2 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

No claims are allowed.

Serial Number: 08/467,584

-4-

Art Unit: 1502


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman, whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday-Friday from 9:30 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703) 308-2927. The fax phone number for this Group is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-2351.

Edward J. Webman:cb
Primary Examiner

Wednesday, November 1, 1995


EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500

Form PTO 948 (Rev. 10-94)

U.S. DEPARTMENT OF COMMERCE - Patent and Trademark Office

Application No.

467584

NOTICE OF DRAFTSPERSON'S PATENT DRAWING REVIEW

PTO Draftpersons review all originally filed drawings regardless of whether they are designated as formal or informal. Additionally, patent Examiners will review the drawings for compliance with the regulations. Direct telephone inquiries concerning this review to the Drawing Review Branch, 703-305-8404.

- The drawings filed (insert date) 6/6/96 are not view and enlarged view not filed separately or properly.
- A. not objected to by the Draftsperson under 37 CFR 1.84 or 1.152. Fig(s) _____
- B. not objected to by the Draftsperson under 37 CFR 1.84 or 1.152 as indicated below. The Examiner will require submission of new, corrected drawings when necessary. Corrected drawings must be submitted according to the instructions on the back of this Notice.
1. DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings:
 Black ink. Color. _____
 Not black solid lines. Fig(s) _____
 Color drawings are not acceptable until petition is granted. Fig(s) _____
2. PHOTOGRAPHS. 37 CFR 1.84(b).
 Photographs are not acceptable until petition is granted. Fig(s) _____
 Photographs not properly mounted (must use bristol board or photographic double-weight paper). Fig(s) _____
 Poor quality (half-tone). Fig(s) _____
3. GRAPHIC FORMS. 37 CFR 1.84(c).
 Chemical or mathematical formula not labeled as separate figure. Fig(s) _____
 Group of waveforms not presented as a single figure using common vertical axis with time extending along horizontal axis. Fig(s) _____
 Individual not defined with a separate letter designation and center in the vertical axis. Fig(s) _____
4. TYPE OF PAPER. 37 CFR 1.84(d).
 Paper not flexible, strong, white, smooth, lustrous, and durable. Sheet(s) _____
 Erasures, alterations, overwritings, interlineations, cracks, creases, and folds copy machine marks not acceptable. Fig(s) _____
 Other: _____ will appear as too acceptable (too thin). Fig(s) _____
5. SIZE OF PAPER. 37 CFR 1.84(d). Acceptable sizes:
 21.6 cm. by 27.9 cm. (8 1/2 by 11 inches)
 21.6 cm. by 33.0 cm. (8 1/2 by 13 inches)
 21.6 cm. by 27.9 cm. (8 1/2 by 11 inches)
 21.6 cm. by 29.7 cm. (DIN size A4)
 All drawing sheets of the same size. Sheet(s) _____
 Drawing sheet not an acceptable size. Sheet(s) _____
6. MARGINS. 37 CFR 1.84(e). Acceptable margins:
 Top: 2.5 cm. (1")
 Bottom: 2.5 cm. (1")
 Left: 2.5 cm. (1")
 Right: 2.5 cm. (1")
7. REMINDER. Specification may require revision to correspond to drawing changes.
 All views not grouped together. Fig(s) _____
 Views connected by projection lines or lead lines. Fig(s) _____
 Partial views. 37 CFR 1.84(b) 2. _____
8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i).
 Words do not appear on a horizontal, left-to-right fashion when page is either upright or turned so that the top becomes the right side, except for graphs. Fig(s) _____
9. SCALE. 37 CFR 1.84(k).
 Scale not large enough to show mechanism with crowding when drawing is reduced in size to two-thirds in reproduction. Fig(s) _____
 Indication such as "actual size" or scale 1/2" not permitted. Fig(s) _____
10. CHARACTER OF LINES, NUMBERS, & LETTERS. 37 CFR 1.84(l).
 Lines, numbers, & letters not uniformly thick and well defined. Fig(s) _____
 Indefinable, indistinct, except for color. Fig(s) _____
11. SHADING. 37 CFR 1.84(m).
 Solid black shading not permitted. Fig(s) _____
 Shading lines, spire, rough and blurred. Fig(s) _____
12. NUMBERS, LETTERS, & REFERENCE CHARACTERS. 37 CFR 1.84(n).
 Numbers and reference characters not plain and legible. 37 CFR 1.84(n)(1) Fig(s) _____
 Numbers and reference characters not oriented in same direction as the view. 37 CFR 1.84(n)(2) Fig(s) _____
 English alphabet not used. 37 CFR 1.84(n)(3) Fig(s) _____
 Numbers, letters, and reference characters do not measure at least .32 cm. (1/8 inch) in height. 37 CFR 1.84(n)(4) Fig(s) _____
13. LEAD LINES. 37 CFR 1.84(o).
 Lead lines cross each other. Fig(s) _____
 Lead lines missing. Fig(s) _____
14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.84(p).
 Sheets not numbered consecutively, and in numerical order, beginning with number 1. Sheet(s) _____
15. NUMBER OF VIEWS. 37 CFR 1.84(q).
 Views not numbered consecutively, and in numerical order, beginning with number 1. Fig(s) _____
 View numbers not preceded by the above shading. Fig(s) _____
16. CORRECTIONS. 37 CFR 1.84(r).
 Corrections not made from prior PTO 948. Fig(s) _____
17. DESIGN DRAWING. 37 CFR 1.152.
 Surface shading shown not appropriate. Fig(s) _____
 Solid black shading not used for color contrast. Fig(s) _____

COMMENTS:



44/ Prior Art
GO 1502
200.93311.DIV

UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Application of: Benjamin OSHLACK et al.
Serial No.: 08/467,584
Filed: June 6, 1995
For: CONTROLLED RELEASE OXYCODONE
COMPOSITIONS

NOV 1 1995

RECEIVED

INFORMATION DISCLOSURE STATEMENT

Hon. Commissioner of
Patents and Trademarks
Washington, D.C. 20231

October 13, 1995

Sir:

Applicants hereby submit PTO Form 1449 which lists references cited during the prosecution of the priority applications U.S. Serial No. 07/800,549 filed November 27, 1991 and 08/081,302 filed June 18, 1993. Copies of the references cited were submitted during the prosecution of the parent applications.

This Information Disclosure Statement is being filed prior to the issuance of the first Office Action, therefore, it is respectfully submitted that no fee is due.

It is respectfully requested that these references be considered and made of record.

Respectfully submitted,

STEINBERG, RASKIN & DAVIDSON, P.C.

Clifford M. Davidson
Clifford M. Davidson
Reg. No. 32,728
James R. Crawford
Reg. No. 34,153

Steinberg, Raskin & Davidson, P.C.
1140 Avenue of the Americas
New York, New York 10036
(212) 768-3800

I hereby certify that this correspondence and/or fee is
being deposited with the United States Postal Service
as first class mail in an envelope addressed to:
"Commissioner of Patents and Trademarks,
Washington, D.C. 20231" on October 13, 1995.
STEINBERG, RASKIN & DAVIDSON, P.C.
BY: *James R. Crawford*

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Sheet 1 of 1

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 200.93311.DIV		SERIAL NO. 08/467,584	
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT Benjamin OSHLACK, et al.		FILING DATE June 6, 1995	
				GROUP 1502			
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE	
<i>OP</i> <i>OP</i>	AA 4 8 6 2 5 9 8	8/89	Oshlack	424	470	NOV 1 1995 RECEIVED	
	AB 4 9 9 0 3 4 1	2/91	Goldie et al.	424	484		
	AC 5 2 6 6 3 3 1	11/30/93	Oshlack et al.	424	468		
	AD						
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FOREIGN PATENT DOCUMENTS							
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION	
						YES	NO
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AN							
AO							
AP							
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
AR							
AS							
AT							
EXAMINER <i>C. L.</i>				DATE CONSIDERED <i>12/95</i>			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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05/40/7, 564 05/06/70 00000000

B 20093311.DIV

EXAMINER
WEBMAN, E

1561/1226

STEINBERG RASKIN & DAVIDSON
1140 AVENUE OF THE AMERICANS
NEW YORK NY 10036

APT UNIT	PAPER NUMBER
	5

DATE MAILED:

EXAMINER INTERVIEW SUMMARY RECORD

12/26/95

All participants (applicant, applicant's representative, PTO personnel):

(1) Mr. C. M. Davidson (3) _____

(2) E. Webman (4) _____

Date of interview 12/18/95

Type: ☒ Telephonic ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☐ No. If yes, brief description: _____

Agreement ☒ was reached with respect to some or all of the claims in question. ☐ was not reached.

Claims discussed: 1, 2

Identification of prior art discussed N/A N/A

Description of the general nature of what was agreed to if an agreement was reached, or any other comments: to bring the case into
condition for allowance, it was agreed to delete 'substantially' in claims 1, 2.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

Unless the paragraphs below have been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW (e.g., items 1-7 on the reverse side of this form). If a response to the last Office action has already been filed, then applicant is given one month from this interview date to provide a statement of the substance of the interview.

☐ It is not necessary for applicant to provide a separate record of the substance of the interview.

☒ Since the examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action.

E. Webman
Examiner's Signature



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO
08/467,584	06/06/95	OSHLACK	B 20093311.DIV
			EXAMINER
			WEBMAN, R
15M1/1226			
STEINBERG RASKIN & DAVIDSON			
1140 AVENUE OF THE AMERICANS			
NEW YORK NY 10036			
		DATE MAILED	12/26/95

NOTICE OF ALLOWABILITY

PART I

1. ☒ This communication is responsive to REPLY PHONE CALL OF 12/14/95.
2. ☒ All the claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.
3. ☒ The allowed claims are 1, 2.
4. ☐ The drawings filed on _____ are acceptable.
5. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received. ☐ not been received. ☐ been filed in parent application Serial No. _____ filed on _____.
6. ☒ Note the attached Examiner's Amendment.
7. ☒ Note the attached Examiner Interview Summary Record, PTOL-413.
8. ☒ Note the attached Examiner's Statement of Reasons for Allowance.
9. ☐ Note the attached NOTICE OF REFERENCES CITED, PTO-892.
10. ☒ Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

PART II

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

1. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
2. ☒ APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
 - a. ☒ Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No. 3. CORRECTION IS REQUIRED.
 - b. ☐ The proposed drawing correction filed on _____ has been approved by the examiner. CORRECTION IS REQUIRED.
 - c. ☐ Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
 - d. ☐ Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

Attachments:

- ☒ Examiner's Amendment
- ☒ Examiner Interview Summary Record, PTOL-413
- ☒ Reasons for Allowance
- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Citation, PTO-1449

- Notice of Informal Application, PTO-152
- Notice re Patent Drawings, PTO-948
- Listing of Bonded Draftsmen
- Other

Serial Number: 08/467584
Art Unit: 1502

-2-

The following is an Examiner's Statement of Reasons for Allowance: None of the references of record singly anticipate or in combination motivate one with ordinary skill in the art to formulate the particular method for reducing the dosage of oxycodone as set forth in the claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Authorization for this Examiner's Amendment was given in a telephone interview with Mr. C. M. Davidson on 12/18/95.

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

In claim 1 line 1 and claim 2 line 1 delete 'substantially'.

Edward J. Webman
December 24, 1995


EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500

'042 - 64


**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

 Address: Box ISSUE FEE
 COMMISSIONER OF PATENTS AND TRADEMARKS
 Washington, D.C. 20231

15M1/1226

 STEINBERG RASKIN & DAVIDSON
 1140 AVENUE OF THE AMERICAS
 NEW YORK NY 10036

**NOTICE OF ALLOWANCE
AND ISSUE FEE DUE**
☐ Note attached communication from the Examiner

☐ This notice is issued in view of applicant's communication filed _____

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/167,584	06/06/95	003	WEDMAN, B 1502	12/26/95

 Final Name of Applicant: **OSHLACK, BENJAMIN**
 TITLE OF INVENTION: **CONTROLLED RELEASE OXYCODONE COMPOSITIONS**

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
20093311-DIV	424-468-000	526	UTILITY	NO	\$1250.00	03/26/96

**THE APPLICATION IDENTIFIES ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.
PROSECUTION ON THE MERITS IS CLOSED.**

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

- I. Review the SMALL ENTITY Status shown above.
 If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
- If the status is changed, pay twice the amount of the FEE DUE shown above and notify the patent and Trademark Office of the change in status, or
 - If the Status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- Pay FEE DUE shown above, or
- File verified statement of Small Entity Status before, or with, pay of 1/2 the FEE DUE shown above.

- II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.

- III. All communications regarding this application must give series code (or filing date), serial number and batch number. Please direct all communication prior to issuance to Box ISSUE FEE unless advised to contrary.

IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PATENT AND TRADEMARK OFFICE COPY

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200.93311.DIV

UNITED STATES PATENT & TRADEMARK OFFICE

Re: Application of: Benjamin OSHLACK et al.
Serial No.: 08/467,584
Filed: June 6, 1995
For: **CONTROLLED RELEASE OXYCODONE
COMPOSITIONS**

SUBMISSION OF FORMAL DRAWINGS

Commissioner of Patents and Trademarks
Washington, D.C. 20231

January 17, 1996

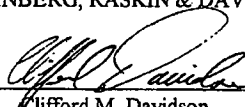
Sir:

Applicants submit herewith formal drawings in connection with the above-identified patent application.

If it is determined that any further fees are due at this time, the Commissioner is hereby authorized to charge any such fees to Deposit Account No. 19-4210.

Respectfully submitted,

STEINBERG, RASKIN & DAVIDSON, P.C.

By 
Clifford M. Davidson
Reg. No. 32,728

Steinberg, Raskin & Davidson, P.C.
1140 Avenue of the Americas
New York, New York 10036
(212) 768-3800

I hereby certify that this correspondence and/or fee is being deposited with the United States Postal Service as "first class mail" in an envelope addressed to "Commissioner of Patents and Trademarks, Washington, D.C. 20231" on January 17, 1996.
STEINBERG, RASKIN & DAVIDSON, P.C.

BY: 

'042 - 66

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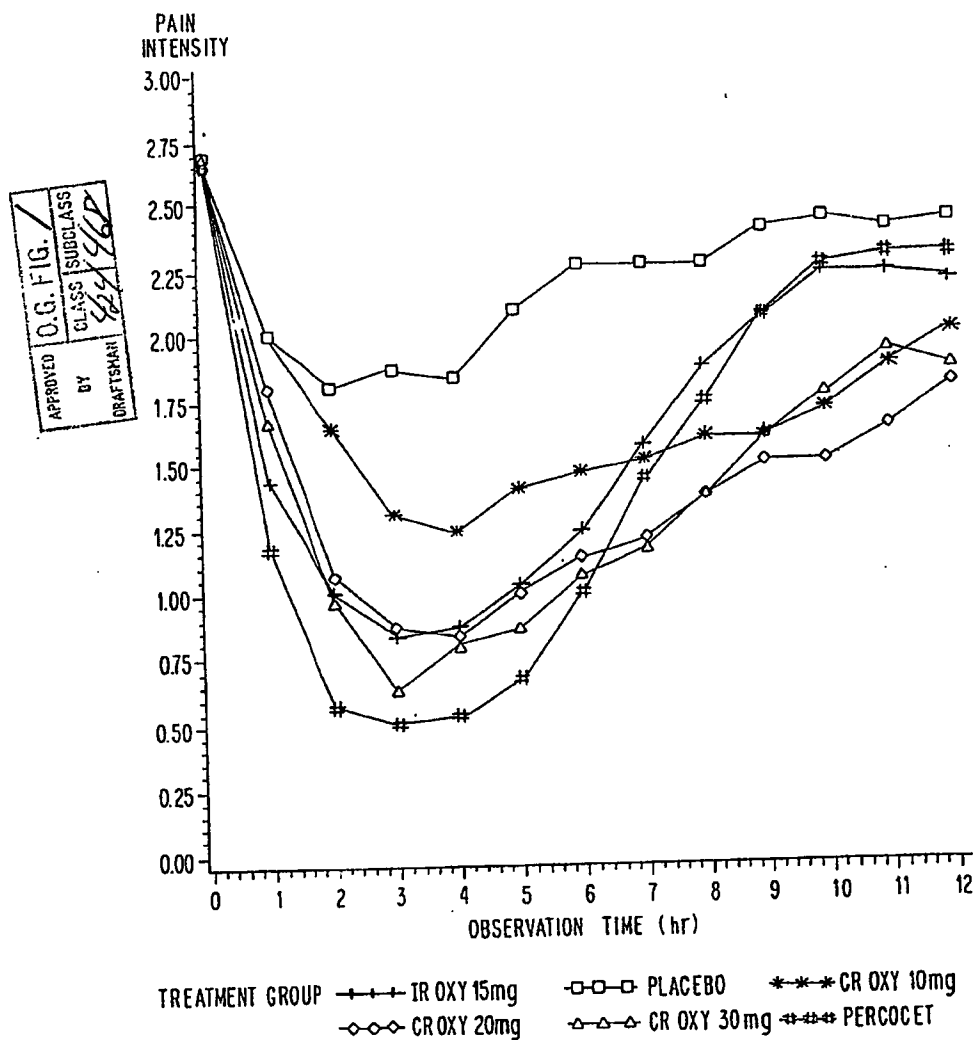


FIG. 1

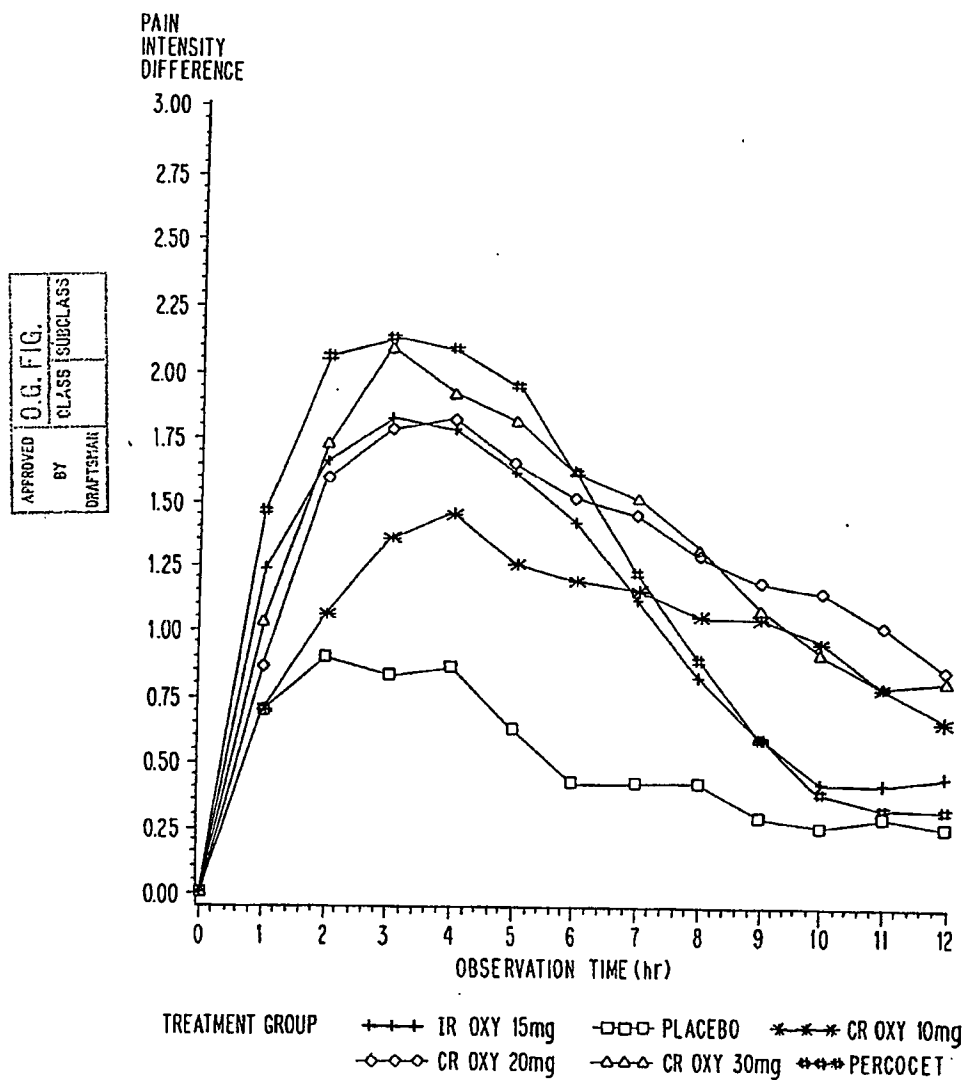


FIG.2

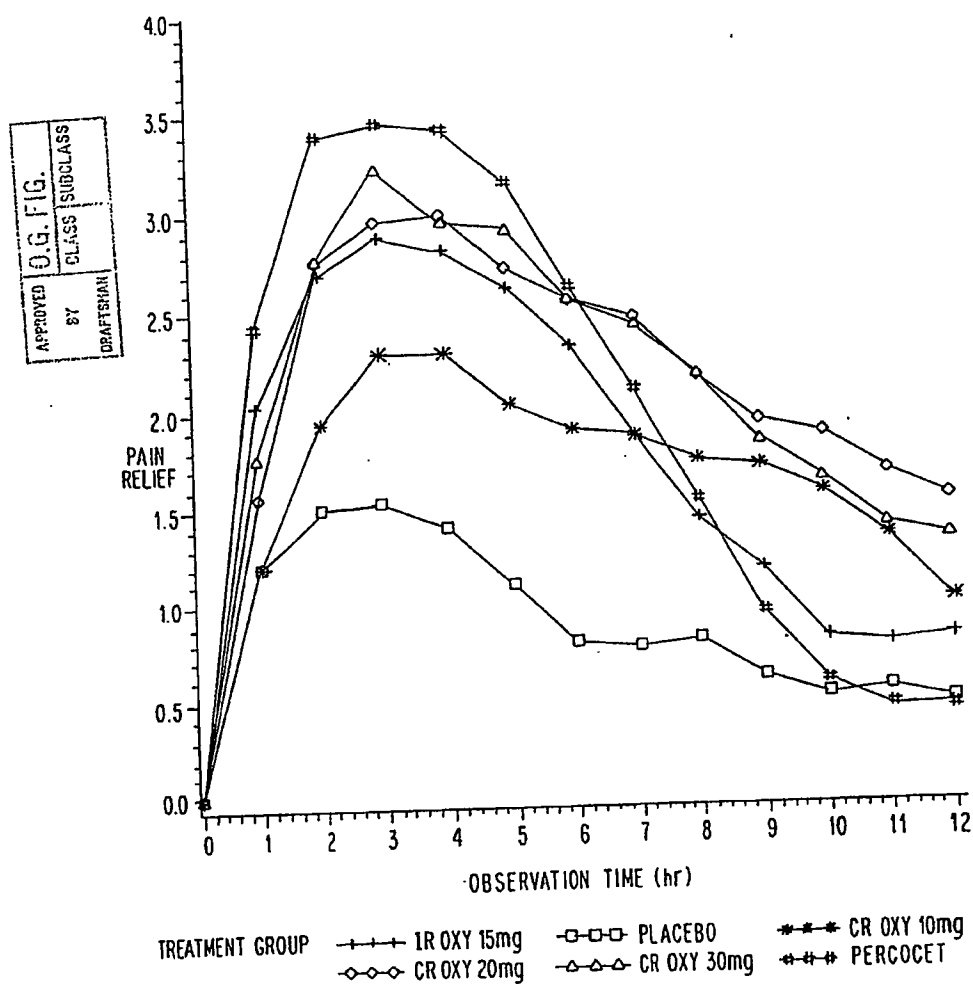


FIG. 3

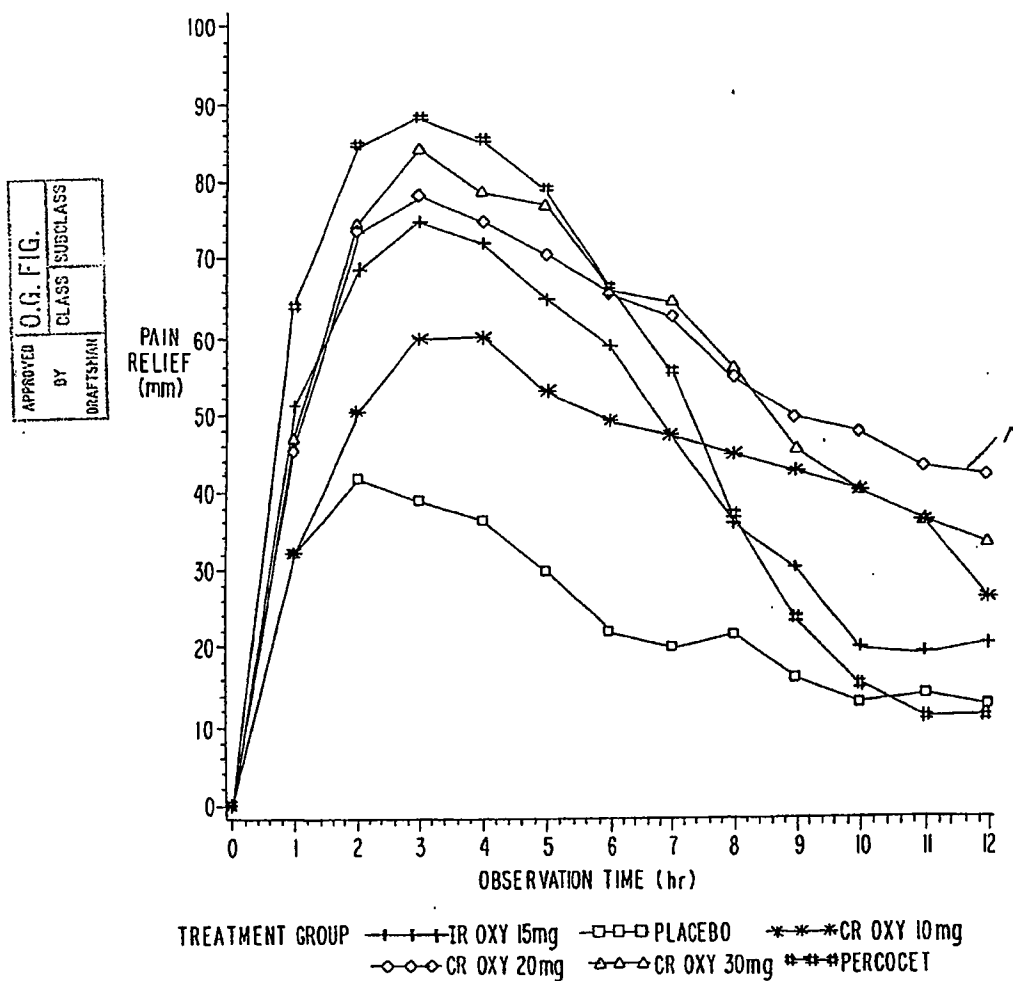
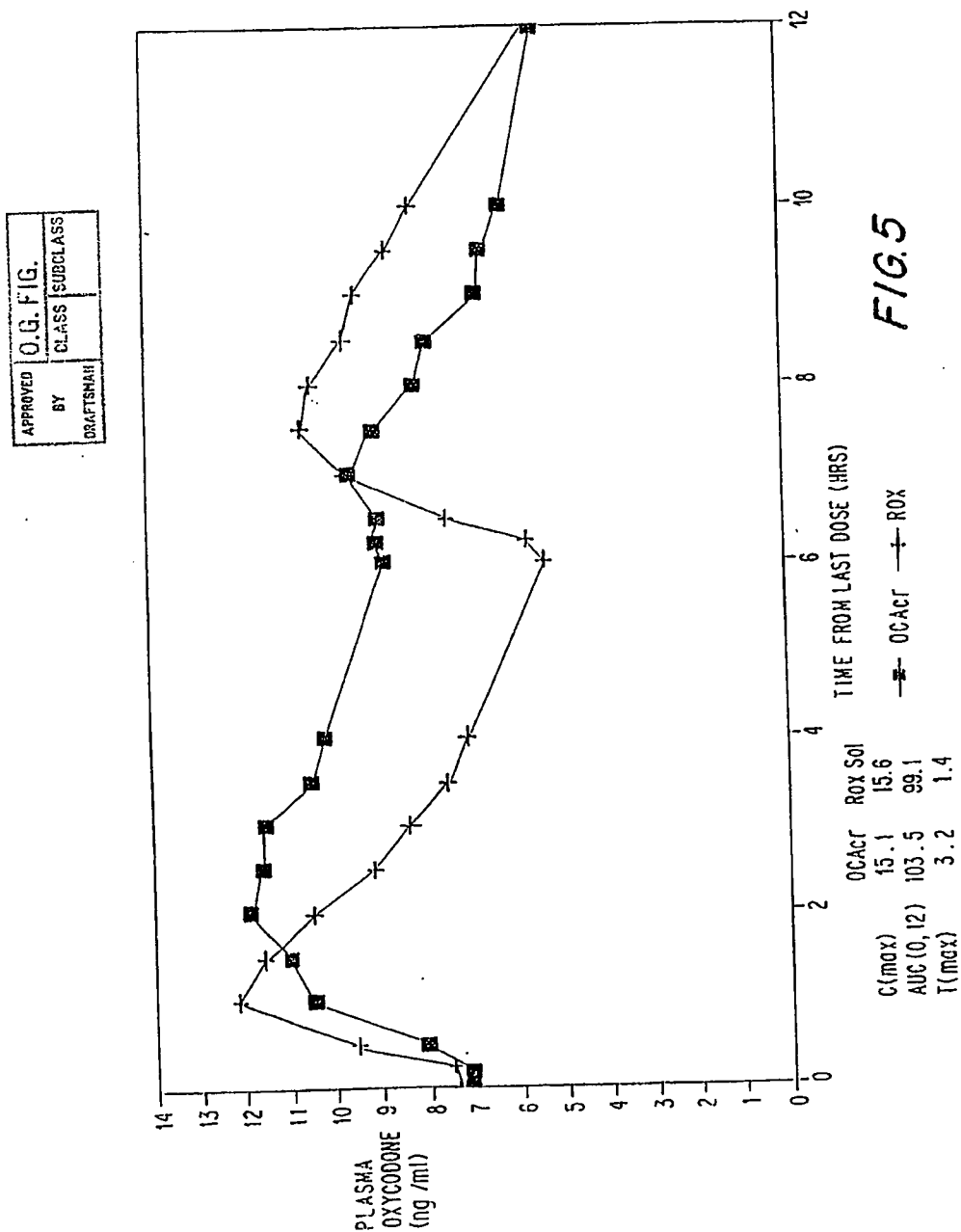


FIG. 4



PART B—ISSUE FEE TRANSMITTAL

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE. Blocks 2 through 6 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advance orders and notification of maintenance fees will be mailed to addressee entered in Block 3 unless you direct otherwise, by: (a) specifying a new correspondence address in Block 3 below; or (b) providing the PTO with a separate "FEE ADDRESS" for maintenance fee notifications with the payment of Issue Fee or thereafter. See reverse for Certificate of Mailing.

1. CORRESPONDENCE ADDRESS

STEINBERG RASKIN & DAVIDSON
1140 AVENUE OF THE AMERICAS
NEW YORK NY 10036

2. INVENTOR(S) ADDRESS CHANGE (Complete only if there is a change)

INVENTOR'S NAME
Street Address
City, State and ZIP Code

CO-INVENTOR'S NAME
Street Address
City, State and ZIP Code

☐ Check if additional changes are on reverse side

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/467,584	06/06/95	002	WEBMAN, E	1502 12/26/95

3. Correspondence address change (Complete only if there is a change)

Steinberg, Raskin & Davidson, P.C.
1140 Avenue of the Americas
New York, New York 10036
Attn: Clifford M. Davidson

4. For printing on the patent front page, list the names of not more than 3 registered patent attorneys or agents OR, alternatively, the name of a firm having as a member a registered attorney or agent. If no name is listed, no name will be printed.

1. Steinberg, Raskin & Davidson, P.C.
2.
3.

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
20003311 DIV	424-468 000	S26	UTILITY	NO	\$1250.00	03/26/96

DO NOT USE THIS SPACE

050 HH 01/26/96 08467584 1 561 30.00 CK
050 HH 01/26/96 08467584 1 142 1,250.00 CK

5. ASSIGNMENT DATA TO BE PRINTED ON THE PATENT (print or type)

(1) NAME OF ASSIGNEE:
Euro-Celtique, S.A.

(2) ADDRESS (CITY & STATE OR COUNTRY):
122, Bd de la Petrusse, L-2330 LUXEMBOURG

☐ This application is NOT assigned.
☐ Assignment previously submitted to the Patent and Trademark Office.
☐ Assignment is being submitted under separate cover. Assignments should be directed to Box ASSIGNMENTS.

PLEASE NOTE: Unless an assignee is identified in Block 5, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

6a. The following fees are enclosed:
☒ Issue Fee ☒ Advance Order - # of Copies 10

6b. The following fees should be charged to:
DEPOSIT ACCOUNT NUMBER 19-4210
(ENCLOSE PART C)
☐ Issue Fee ☐ Advance Order - # of Copies
☒ Any Delinquencies in Enclosed Fees

The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee to the application identified above.

(Authorized Signature) (Date)
01/17/96

NOTE: The Issue Fee will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the Patent and Trademark Office.

TRANSMIT THIS COPY WITH FEE CERTIFICATE OF MAILING ON REVERSE

'042 - 72

*The
United
States
of
America*



PTO-1584

PTO UTILITY GRANT
Paper Number 2

**The Commissioner of Patents
and Trademarks**

*Has received an application for a patent
for a new and useful invention. The title
and description of the invention are en-
closed. The requirements of law have
been complied with, and it has been de-
termined that a patent on the invention
shall be granted under the law.*

Therefore, this

United States Patent

*Grants to the person or persons having
title to this patent the right to exclude
others from making, using or selling the
invention throughout the United States
of America for the term of seventeen
years from the date of this patent, sub-
ject to the payment of maintenance fees
as provided by law.*

Bence Lehman
Commissioner of Patents and Trademarks
Linda P. Wilson

Attest

Staple Issue Slip Here

POSITION	ID NO.	DATE
CLASSIFIER	53	29 JUN 1995
EXAMINER	432	11-20-95
TYPIST	up	7-22-95
VERIFIER	407	7-27-95
CORPS CORR.		
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FILE MAINT.		
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INDEX OF CLAIMS

Claim	Date
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SYMBOLS

✓ Rejected

— Allowed

— (Through numbers) Canceled

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I Interference

A Appeal

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Claim	Date
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SEARCHED ✓			
Class	Sub.	Date	Exmr.
424	456 464 465 468-69 470 487-88 494-98 494-98 494	10/99	gpl
70	DME	12/95	gpl

SEARCH NOTES ✓		
	Date	Exmr.
NONG	12/95	gpl

INTERFERENCE SEARCHED ✓			
Class	Sub.	Date	Exmr.
424	486-488 468-470 404-65 494-49 494 496-498	12/95	gpl

PATENT APPLICATION

08/467584



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APPROVED FOR LICENSE

INITIALS JUL 05 95

Date
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CONTENTS



- | | | |
|--------------|-----------------------------------|-----------------|
| | 1. Application <i>435</i> papers. | |
| | 2. <i>Pre a</i> | <i>Junk</i> |
| <i>10-16</i> | 3. <i>Ref (3 mac)</i> | <i>11-3-95</i> |
| | 4. <i>Pre Art</i> | <i>10-16-95</i> |
| | 5. <i>Interview Summary</i> | <i>12/26/95</i> |
| <i>12-26</i> | 6. <i>Exam Amet/B</i> | <i>12/24/95</i> |
| <i>1/31</i> | 7. <i>Formal (5 shis) set</i> | <i>1/18/96</i> |
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